

Substitute for forms 1449A/PTO & 1449B/PTO

ATTORNEY'S DKT No.
028723-385APPLICATION No.
10/641,149FIRST INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Allan J. Tobin et al.FILING DATE
August 15, 2003GROUP
Unassigned

U.S. PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
<i>[initials]</i>	4,751,181		Keene	06-14-1988
<i>[initials]</i>	4,487,830		Coates et al.	12-11-1984
<i>[initials]</i>	5,792,620		Lernmark et al.	08-11-1998
<i>[initials]</i>	5,998,366		Tobin et al.	12-07-1999

FOREIGN PATENT DOCUMENTS

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation Yes No
<i>[initials]</i>	0 383 129		Europe	08-22-1990	
<i>[initials]</i>	90/07117		International Publication	06-28-1990	
<i>[initials]</i>	92/05446		International Publication	04-02-1992	

NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
1 <i>[initials]</i>	PERSSON, et al., Expression of the Neurotransmitter-Synthesizing Enzyme Glutamic Acid Decarboxylase in Male Germ Cells; Molecular and Cellular Biology, pp 4701-4711, Sept 1990, Vol. 10, No.9
2 <i>[initials]</i>	JULIEN, et al. Rat Brain Glutamic Acid Decarboxylase Sequence Deduced from a Cloned cDNA; Journal of Neurochemistry, 54:703-705, 1990.
3 <i>[initials]</i>	LEGAY, et al., Evidence for Two Distinct Forms of Native Glutamic Acid Decarboxylase in Rat Brain Soluble Extract: An Immunoblotting Study; Journal of Neurochemistry, 48:1022-1026, 1987
4 <i>[initials]</i>	MICHELSSEN, et al., Cloning, characterization, and autoimmune recognition of rat islet glutamic acid decarboxylase in insulin-dependent diabetes mellitus, Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 8754-8758, October 1991
5 <i>[initials]</i>	JULIEN, et al., Molecular Cloning, Expression and in situ Hybridization of Rat Brain Glutamic Acid Decarboxylase Messenger RNA; Neuroscience Letters, 73:173-180, 1987
6 <i>[initials]</i>	KOBAYASHI, et al., Glutamic Acid Decarboxylase cDNA: Nucleotide Sequence Encoding an Enzymatically Active Fusion Protein; The Journal of Neuroscience, 7(9):2768-2772, 1987.
7 <i>[initials]</i>	SOLIMENA, et al., Autoantibodies to Gaba-Ergic Neurons and Pancreatic Beta Cells In Stiff-Man Syndrome: The New England Journal of Medicine, Vol. 322, No. 22, pp. 1555-1560, May 1990
8 <i>[initials]</i>	BAEKESKOV, et al., Identification of the 65K Autoantigen in Insulin-Dependent Diabetes as the GABA-synthesizing Enzyme Glutamic Acid Decarboxylase; Nature, Vol. 347, 151-156, 1990.
9 <i>[initials]</i>	ATKINSON, et al., What Causes Diabetes? Scientific American, pp. 62-71, 1990.
10 <i>[initials]</i>	BAEKESKOV, et al., Revelation of Specificity of 64K Autoantibodies in IDDM Serums by High-Resolution 2-D Gel Electrophoresis; Diabetes, Vol. 38:1133-1141, 1989.
11 <i>[initials]</i>	BAEKESOV, et al., Autoantibodies in Newly Diagnosed Diabetic Children Immunoprecipitate Human Pancreatic Islet Cell Proteins; Nature, 298:167-169, 1982.
12 <i>[initials]</i>	BAEKESKOV, et al., Antibodies to a 64,000 M, Human Islet Cell Antigen Precede the Clinical Onset of Insulin-Dependent Diabetes; J. Clin. Invest., 79:926-934, 1987.
13 <i>[initials]</i>	CHANG, et al., Characterization of the Proteins Purified with Monoclonal Antibodies to Glutamic Acid Decarboxylase; The Journal of Neuroscience, 8(6):2123-2130, 1988
14 <i>[initials]</i>	ZIEGLER, et al. Predicting Type I Diabetes; Diabetes Care, 13:762-775, 1990
15 <i>[initials]</i>	CHRISTIE, et al., Characterization of a cDNA Coding for Rat Glutamic Acid Decarboxylase; Molecular Brain Research 8:193-198, 1990
16 <i>[initials]</i>	ATKINSON, et al., 64000 M, Autoantibodies as predictors of Insulin-Dependent Diabetes; The Lancet, vol. 335:1357-1360, 1990
17 <i>[initials]</i>	CHRISTIE, et al., Cellular and Subcellular Localization of an M, 64,000 Protein Autoantigen in Insulin-Dependent Diabetes; The Journal of Biological Chemistry, 265(1) 376-381 (1990).
18 <i>[initials]</i>	KATAROVA, et al., Molecular Identification of the 62 kd Form of Glutamic Acid Decarboxylase from the Mouse; European Journal of Neuroscience, Vol. 2, No. 3, pp. 190-202, 1990.
19 <i>[initials]</i>	WYBORSKI, et al., Characterization of CDNA Coding for Rat Glutamic Acid Decarboxylase; Molecular Brain Research, 8:193-198, 1990.
20 <i>[initials]</i>	KAUFMAN, et al., Brain Glutamate Decarboxylase Cloned in λ gt-11: Fusion Protein Produces γ -Aminobutyric Acid; Science, Vol. 232:1138-1140, 1986

Substitute for forms 1449A/PTO & 1449B/PTO

ATTORNEY'S DKT NO.
028723-385APPLICATION NO.
10/641,149FIRST INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
Allan J. Tobin et al.FILING DATE
August 15, 2003GROUP
Unassigned

NON PATENT LITERATURE DOCUMENTS

Examiner
Initials

Include name of author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.

- 1 BU, et al., Two Human Glutamate Decarboxylases, 65-kDa GAD and 67-kDa GAD, Are each Encoded by a Single Gene, Proceedings of the National Academy of Sciences, Vol. 89, No. 6, pp 2115-2119, 1992
- 2 KARLSEN, et al., Cloning and Primary Structure of a Human Islet Isoform of Glutamic Acid Decarboxylase from Chromosome 10, Proceedings of the National Academy of Sciences, Vol. 88, No. 19, pp. 8337-8341, 1991
- 3 KARLSEN, et al., Immune Recognition and Gene Expression of Islet Glutamic Acid Decarboxylase, Clinical Research, Vol. 39, No. 2, p. 173A, 1991
- 4 Expression of Cloned Genes in Cultured Mammalian Cells, 16.1-16.56
- 5 Detection and Analysis of Proteins Expressed from Cloned Genes, 18.1-18.26
- 6 MULLIGAN et al., Selection for Animal Cells That Express the *Escherichia coli* Gene Coding for Xanthine-Guanine, Proceedings of the National Academy of Sciences, Vol. 78, No. 4, pp. 2072-2076, 1981
- 7 KINGSMAN et al., The Production of Mammalian Proteins in *Saccharomyces cerevisiae*, T/BTECH, pp.53-57, 1987
- 8 HOWELL et al., Vaccination Against Experimental Allergic Encephalomyelitis with T Cell Receptor Peptides, Science, Vol. 246, pp. 668-670, 1989
- 9 WRAITH et al., Antigen Recognition in Autoimmune Encephalomyelitis and the Potential for Peptide-Mediated Immunotherapy, Cell, Vol. 59, pp. 247-255, 1989
- 10 HUANG et al., Molecular Cloning and Amino Acid Sequence of Brain L-glutamate Decarboxylase, Proceedings of the National Academy of Sciences, Vol. 87, pp. 8491-8495, 1990
- 11 BAEKKESKOV et al., Autoantibodies to a 64-kilodalton Islet Cell Protein Precede the Onset of Spontaneous Diabetes in the BB Rat, Science, Vol. 224, pp. 1348-1350, 1984
- 12 GERLING et al., Islet Cell and 64K Autoantibodies are Associated with Plasma IgG in Newly Diagnosed Insulin-Dependent Diabetic Children, Vol., 137, No. 12, pp. 3782-3785, 1986
- 13 ATKINSON, et al. Autoantibodies in Nonobese Diabetic Mice Immunoprecipitate 64,000-M, Islet antigen, Diabetes, Vol. 37, pp. 1587-1590, 1988
- 14 TUOMI et al., Antibodies to Glutamic Acid Decarboxylase Reveal Latent Autoimmune Diabetes Mellitus in Adults With a Non-Insulin-Dependent Onset of Disease, Diabetes, Vol. 42, pp. 359-362, 1993
- 15 ZIMMET et al., Crucial Points at Diagnosis Type 2 diabetes or slow type 1 diabetes, Diabetes Care, Vol. 22, Supplement 2, pp. B59-B64, 1999
- 16 SCHRANZ et al., Immunology in diabetes: an update, Diabetes Metab. Rev. Vol. 14, No. 1 pp. 3-29, 1998
- 17 HAGOPIAN et al., Quantitative Assay Using Recombinant Human Islet Glutamic Acid Decarboxylase (GAD65) Shows That 64K Autoantibody Positivity at Onset Predicts Diabetes Type, J. Clin. Invest., Vol. 91, pp. 368-374, 1993
- 18 ZIMMET et al., Antibodies to glutamic acid decarboxylase in the prediction of insulin dependency, Diabetes Res. Clin. Pract., Vol. 34, pp. S125-131, 1996
- 19 ZIMMET et al., Latent autoimmune diabetes mellitus in adults (LADA): the role of antibodies to glutamic acid decarboxylase in diagnosis and prediction of insulin dependency, Diabet. Med. Vol. 11, No. 3, pp. 299-303, 1994 (abstract)

Examiner
SignatureDate
Considered

3/14/04

EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 809. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.